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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2017-D-5225]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0752. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-45, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Foreign Supplier Verification Programs (FSVP) for Food Importers--21 CFR part 1, subpart L

OMB Control Number 0910-0752--Extension

This information collection supports FDA regulations in 21 CFR part 1, subpart L (21 CFR 1.500 through 1.514 (§§ 1.500 through (§§ 1.514)), which help to implement section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a). Section 805 authorizes the Agency's FSVP and establishes requirements applicable to imported food. Respondents to the information collection are importers, as defined in section 805(a)(1) of the FD&C Act. The regulations are intended to provide verification that imported food is produced in compliance with statutory requirements that include the implementation of appropriate risk-based preventive controls. The regulations also establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions. To assist respondents with understanding the requirements we have developed Agency guidance, available at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.

Specifically, regulations in § 1.501 set forth the applicability of requirements for FSVP, while regulations in §§ 1.502 through 1.508, prescribe specific activities for developing, maintaining, and following an FSVP; as well as for evaluating compliance and for identifying and correcting hazards. Finally, regulations in § 1.509 identify required data elements applicable to food products offered for importation into the United States, while regulations in § 1.510

govern required records, providing that records be made available to FDA upon request and that records be maintained electronically. On May 10, 2021, FDA launched the FSVP Importer Portal for FSVP Records Submission as a means for importers to upload FSVP records electronically and submit them to the Agency, after receiving a request for records from FDA. The portal may be found at https://www.access.fda.gov/, and a user guide is available at https://www.fda.gov/media/148312/download.

In the *Federal Register* of January 28, 2022 (87 FR 4607), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

| Activity; 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden Per Response | Total Hours |
|---|---|---|---|---|---|
| Exemption for food for research; 1.501(c) | 36,360 | 40 | 1,454,400 | 0.083 (5 minutes) | 120,715 |
| Identifier for filing with U.S. Customs and Border Protection; 1.509 | 56,800 | 157 | 8,917,600 | 0.02 (1.2 minutes) | 178,352 |
| Total | | | 10,372,000 | | 299,067 |

[1] There are no capital costs or operating and maintenance costs associated with the information collection.

Table 2.--Estimated Annual Recordkeeping Burden[1,2]

| Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| Controls for low-acid canned foods; 1.502(b) | 2,443 | 4 | 9,772 | 1 | 9,772 |
| Hazard determinations, controls, and audits; 1.504, 1.506, 1.511 | 56,800 | 87.74 | 4,984,036 | 0.38 (23 minutes) | 1,917,174 |
| Written assurances for food produced under dietary supplement current good manufacturing practices; 1.511 | 11,701 | 2.88 | 33,664 | 2.25 | 75,744 |
| Document very small importer/certain small foreign supplier status; 1.512(b)(1) | 50,450 | 1 | 50,450 | 1 | 50,450 |
| Written assurances associated with very small importer/certain small foreign supplier; 1.512(b)(3) | 50,450 | 2.79 | 141,084 | 2.25 | 317,439 |
| Total | | | 5,219,006 | | 2,370,579 |

[1] There are no capital costs or operating and maintenance costs associated with the information collection.
[2] Figures have been rounded to the nearest one hundredth.

Upon evaluation of the information collection, we are retaining the currently approved burden estimates.

Dated: April 5, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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